Basic Building Block Profile

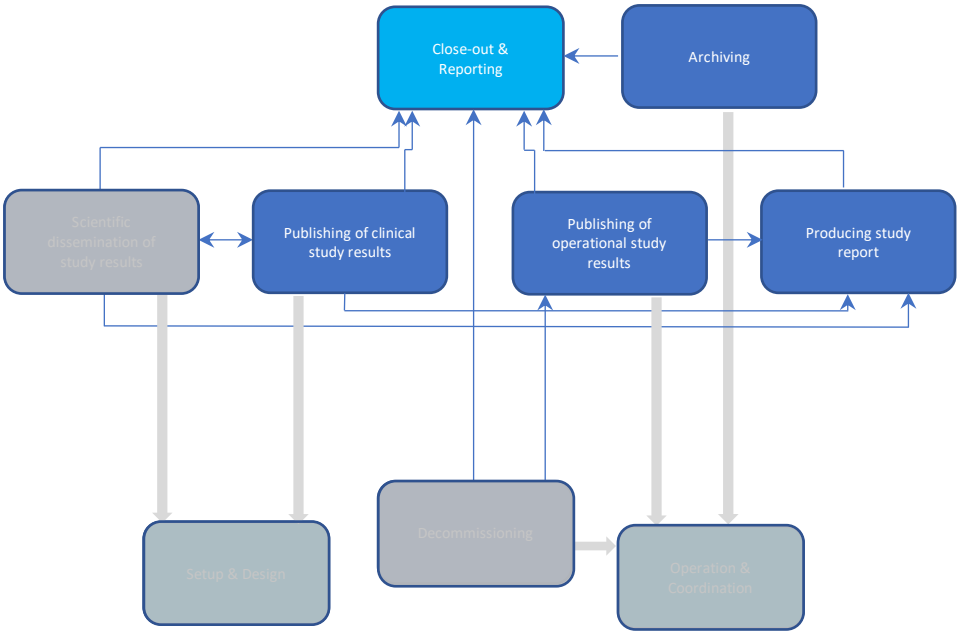
Building Block: Close-out & Reporting

Vision

Close-out & Reporting is responsible for external communication and provides information on Trials@Home in form of study reports and scientific communications. Additionally, archiving of study-relevant data and decommissioning of study-related software and hardware is also in this BBB's responsibility. A crucial prerequisite therefore is a solid data base. Based on the data, the compilation of final reports requires an envrionment which enables collaborative writing. The submission management should be integrated into the study's digital platform to use the study's central contact point for the publishing of study-relevant information.
One key aspect of Close-out & Reporting will be the publication of – optimally automatically generated – clinical and operational study reports based on the data provided by the shared digital platform and the clinical trials management system in form of raw data (for example eCRFs) or the TMF as well as clinical oversight data (provided by *Operation & Coordination*). As a version-controlled repository for key documents, the global document management system is also potentially suited for the archiving task of *Close-out & Reporting*. It must, however, also be available beyound the end of the study.

Activities involved

Activities not relevant for the RFP are greyed out.



The research leading to these results has received support from the EU/EFPIA Innovative Medicines Initiative [2] Joint Undertaking (H2020-JTI-IMI2) Trials@Home grant n° 831458.

Included activities in the RFP:

The following activities are included in the RFP:

- **Archiving of study data**
  - Clinical study data
  - Operational study data
  - Allow to exclude data (GDPR)
  - Data may have to be merged from several repositories
  - Options for cloud / physical archiving
  - Access mechanism to support remote audits
  - Automatic generation of overview/glossary file

- **Automatic generation of study reports**
  - Provide templates that meet requirements for study reports
  - Defined interfaces to access relevant data in data repository
  - Provide reasonable overview prior to report generation
  - Allow to select/unselect data
  - Automatic compilation of clinical study reports
  - Automatic compilation of operational study reports

Excluded activities from the RFP

The activities below are already covered by internal partner and **excluded from the RFP**:

- Decommissioning
- Environment: collaborative report writing

RFP - Knockout Criteria

For the activities included in the RFP we have identified a number of knockout criteria that will exclude the technology vendor in the case that one or more of them are not met.

Archiving of study data

The technology will be rejected if:

1) only providing one way of archiving (several options should be available/selectable)

Clinical study data

The technology will be rejected if:

1) it is not GDPR-compliant (e.g. needs to send data to unsecure servers)

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